

REMARKS

The Invention

The invention features nucleic acids encoding attractin polypeptides and fusion proteins containing attractin polypeptides, vectors containing the nucleic acids, cells containing the vectors, and methods of making the polypeptides and the fusion proteins.

Status of the claims

Claims 1-37 are pending and claims 1-3, 6, and 20-27 are under consideration in this application, claims 4, 5, 7-19, and 28-37 have been withdrawn from consideration on the grounds that they are allegedly drawn to separate inventions. Claims 2, 3, 6, and 24-27, if written in independent form, would be allowable. Claims 1 and 20-23 stand rejected. Claims 38-46 are newly added. After entry of the amendments made herein claims 1-46 will be pending and claims 1-3, 6, 20-27, and 38-46 will be under consideration in this application.

New claims 38-40 are supported by the specification (e.g., claim 1 as originally filed and page 21, lines 11-28). New claims 41-45 are supported by the specification, e.g., at page 19, line 31, to page 21, line 10). New claim 46 is supported by the specification, e.g., at page 30, lines 13-32.

Applicants respectfully draw the Examiner's attention to the fact that, as shown by the specification (e.g., Examples 2, 8, and 9), the nucleic acids with SEQ ID NOs: 1, 11, 13, and 19 are merely splice variants of each other and correspond to mRNAs transcribed from a single gene and the polypeptides with SEQ ID NOs: 2, 10, 12, and 18 are similarly splice variants all encoded by the same single gene. Moreover, as evidenced by newly added claims 38-40, the nucleic acids with SEQ ID NO: 1, 11, 13, and 19 all fall within the scope of claim 1. In light of these considerations, Applicants respectfully request that the Examiner examine the claims under consideration with respect all four splice variants.

Claims dependent on a non-elected claim

In that claim 6 (and claims 24-27) is dependent on non-elected claim 5 (see Office Action, page 2, paragraph 5), claim 6 has been amended to be in independent form. This

amendment is supported by the specification, e.g., at page 22, lines 11-19; page 24, lines 14-23; and claim 5 as originally filed. No new matter is added by this amendment.

Drawings

A set of formal drawings is being sent separately to the Official Draftsperson. Copies of the formal drawings (marked "Copies") are enclosed herewith as a courtesy to the Examiner.

35 U.S.C. § 112, second paragraph, rejection

Claims 1 and 20-23 stand rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

From the comments on page 2, paragraph 7, of the Office Action, Applicants understand the Examiner's position to be that claims 1 and 20-23 are indefinite because the term "hybridizes under highly stringent conditions" is ambiguous. While not necessarily agreeing with this position, in order to expedite prosecution of the instant application, Applicants have amended claim 1 to specify particular hybridization conditions. This amendment, which is supported by the specification, e.g., at page 21, lines 25-28, adds no new matter.

Applicants respectfully submit that the above amendment has enhanced the clarity of claim 1 and claims dependent on it and thus request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 112, first paragraph, rejections

Claims 1 and 20-23 stand rejected on the grounds that: (a) the specification allegedly does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; and (b) they allegedly contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants understand from the comments on page 3, line 1, and page 5, line 12, of the Office Action the Examiner's main concern to be that the DNAs covered by claim 1 are limited only by their ability to hybridize to any nucleic acid that encodes SEQ ID NO:12 (i.e., including

all degenerate variants of SEQ ID NO: 13) rather than by their ability to hybridize to a specific nucleic acid sequence (i.e., SEQ ID NO:13). Applicants understand the Examiner's position, in view of this limitation, to be that: (a) claim 1 specifies DNAs that would require undue experimentation by one skilled in the art to make and/or use; and (b) the specification does not provide sufficient written description of the DNAs encompassed by claim 1.

While not necessarily agreeing with this position, in order to expedite prosecution of this application, Applicants have amended claim 1 so as to require that the claimed DNA hybridize under the specified conditions to a nucleic acid sequence consisting of SEQ ID NO:13. This amendment, which is supported by the specification, e.g., at page 21, lines 11-28, page 3, line 21, to page 4, line 3, and the claims as originally filed, adds no new matter.

With regard to the issue of written description, Applicants respectfully submit that claim 1 contains, at least, all the requirements for an adequately described "Hybridization" claim as set forth in Example 9 of "The Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, paragraph 1, 'Written Description' Requirements" (the "Written Description Guidelines"). Thus, in conformity with Example 9 of the Written Description Guidelines, the instant specification indicates that an "essential feature of the claimed invention is the isolated nucleic acid that hybridizes under highly stringent conditions to SEQ ID NO:[13] and encodes a protein with a specific function." (see, e.g., page 3, line 21, to page 4, lines 3, of the specification). Moreover, Example 9 of the Written Description Guidelines "the art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing."

Also as required by Example 9 of the Written Description Guidelines, SEQ ID NO:13 is "novel and non-obvious" (see below).

Furthermore, with respect to genus claims, Example 9 of the Written Description Guidelines states that, in that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs" (emphasis added), disclosure of a single species constitutes a representative number of species for the purposes of Written Description. Applicants draw the Examiner's attention to that fact that three more representative species than are required by Example 9 the Written Description Guidelines

(i.e., those with SEQ ID NOs: 1, 11, 19 as well as that with SEQ ID NO:13) are disclosed by the specification (see, e.g., Examples 2, 8, and 9 and Figures 8-14).

With respect to the issue of enablement, Applicant submits that in view of the greatly reduced number of species covered by amended claim 1 and the inclusion of four representative species falling within the scope of the claim, it would not involve undue experimentation for one skilled in the art to establish sequences that conform to the structural and functional requirements of the claim. The Examiner is reminded that:

a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable guidance with respect to the direction in which experimentation should proceed. *In re Wands*, 858 F.2d 731, 736-7 (Fed. Cir. 1988).

In addition, in regard to the comments on page 3, lines 24-33, of the Office Action, Applicants draw the Examiner's attention to the following observations. In that the polypeptides with SEQ ID NOs: 2, 10, 18 (encoded by the nucleic acid sequences with SEQ ID NOs: 1, 11, and 19, respectively) lack internal domains of membrane attractin-2 (SEQ ID NO:12), they are not true fragments of membrane attractin-2 SEQ ID NO: 12 (see, e.g., page, Examples 8 and 9 in the specification). Nevertheless, as smaller polypeptides containing various segments of membrane attractin-2, they are informative with respect to fragments of attractin-2. The polypeptide with SEQ ID NO: 2 ("soluble attractin-1") has the function required by claim 1 (see, e.g., Example 2 in the specification). In that all of the other three polypeptides (i.e., those with SEQ ID NOs: 10, 12, and 18) include the functional domains of soluble attractin-1 as well as additional sequences (see, e.g., Examples 2, 3, 8 and 9 and Figure 4), one skilled in the art would expect that they (and true fragments of membrane attractin-2 analogous to SEQ ID NO:2, SEQ ID NO:10, and SEQ ID NO:18) also would have the activity.

In light of the above considerations, Applicants respectfully submit that the instant specification provides adequate enablement and written description for claims 1 and 20-23 and thus request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

35 U.S.C. §§ 102(a) and 103(a) rejections

Claim 1 stands rejected as allegedly being anticipated by Nagase et al. and claims 20-23 as allegedly being unpatentable over Nagase et al. in view of Darnell et al. Applicants respectfully traverse this rejection.

First, Applicants do not acknowledge that the Nagase et al. reference is prior art with respect to the instant application. Nevertheless, even if the reference is such prior art, Applicants submit that, for the reasons given below, it does not anticipate claim 1.

Applicants understand the Examiner's position to be that be in disclosing a nucleic acid sequence that hybridizes under highly stringent conditions to the complement of a sequence that encodes a polypeptide containing amino acids 978-1429 of SEQ ID NO:12, Nagase et al. discloses the DNA of claim 1. Applicants disagree with this position. Contrary to the assertion on page 5, paragraph 11, of the Office Action, it is far from clear that the protein disclosed by Nagase et al., which is less than one third of SEQ ID NO:12, would inherently have the ability to enhance spreading of a macrophage or monocyte. The Examiner is reminded that

[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). MPEP 2112

Moreover, Applicants understand the Examiner's position to be that Darnell et al. in its general teachings of various aspects of recombinant protein production overcomes the failure of Nagase et al. to teach the embodiments of claims 20-23 and, thus, that the combination of Nagase et al. and Darnell et al. render claims 20-23 obvious. Applicants respectfully submit that, because Darnell et al. does not overcome the infirmity of Nagase et al. with respect to teaching the DNA of claim 1, a combination of Nagase et al. and Darnell et al. cannot render claims 20-23 obvious. Darnell et al. contains no teachings regarding proteins that enhance spreading of macrophages or monocytes, let alone the protein disclosed by Nagase et al. and thus does not provide any more information than Nagase et al. itself as to the ability of the protein to enhance spreading of macrophages or monocytes.

Since the protein disclosed by Nagase et al. does not necessarily have the function required by claim 1, the reference does not anticipate claim 1. Moreover, in that Darnell et al.

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provides no cure for this defect in the disclosure of Nagase et al., the combination of Nagase et al. and Darnell et al. does not render claims 20-23 obvious. In light of these considerations, Applicants respectfully request that the rejections under 35 U.S.C. §§ 102(a) and 103(a) be withdrawn.

CONCLUSION

For the reasons set forth below, Applicants maintain that the claims under consideration patentably define the invention. Applicants request that the Examiner reconsider the rejections as set forth in the Office Action and permit the pending claims to pass to allowance.